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10/567,114

02/03/2006

Valery Khazhmuratovich Zhilov

4874-7000

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85775 7590 07/13/2009

Locke Lord Bissell & Liddell LLP

Attn: IP Docketing

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New York, NY 10281-2101

EXAMINER

LAU, JONATHAN S

ART UNIT

PAPER NUMBER

1623

NOTIFICATION DATE

DELIVERY MODE

07/13/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ptopatentcommunication@lockelord.com

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/567,114 | Applicant(s) ZHILOV ET AL. | |
| | Examiner Jonathan S. Lau | Art Unit 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 Mar 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71-81 is/are pending in the application.
- 4a) Of the above claim(s) 74, 75 and 78-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 71-73, 76 and 77 is/are rejected.
- 7) ☒ Claim(s) 72 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :24 pgs / 03 Feb 2006, 08 Aug 2006, 09 Aug 2006, 01 Nov 2006, 02 Nov 2006.

DETAILED ACTION

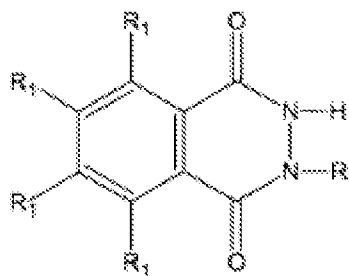
This Office Action is responsive to Applicant's Amendment and Remarks, filed 23 Mar 2009, wherein claims 43-70 are canceled and new claims 71- 81 are added.

This application is the national stage entry of PCT/RU03/00346, filed 04 Aug 2003.

Claims 71- 81 are pending in the current application. Claims 74, 75 and 78-81, drawn to non-elected inventions, are withdrawn. Claims 71-73 (in part) and 76 and 77 are examined on the merits herein.

Election/Restrictions

Applicant's election of Group IX, drawn to a method comprising administering a therapeutically amount of a compound having the general formula



, encompassing canceled claims 52-55 (in part) and new claims 71-73 (in part) and 76 and 77 in the reply filed on 23 Mar 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the

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restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Claims 74, 75 and 78-81 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 23 Mar 2009.

Applicant's election of species of the sodium salt of 5-amino-benzo[d]-3H-pyridazine-1,4-dione in the reply filed on 23 Mar 2009 is acknowledged. This species reads upon new claims 71-73 (in part) and 76 and 77.

Information Disclosure Statement

The IDS mailed 01 Nov 2006 is not considered because the statement is not signed. See 37 CFR 1.33 (b). However, see immediately below regarding the replacement IDS mailed 02 Nov 2006.

References provided in the IDS mailed 02 Nov 2006 to replace the IDS mailed 01 Nov 2006 have been considered, as this statement is signed in accordance with 37 CFR 1.33 (b). The citations for 36 and 64 are interpreted as entries that continue across two pages as indicated on the Examiner initialed IDS.

Claim Objections

Claim 72 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Claim 72 recites “wherein the therapy includes hepatoprotective action”. It is unclear if said hepatoprotective action is an additional type of therapy, thereby broadening the group of therapies of claim 71, or if the method of claim 71 further comprises hepatoprotective action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 71-73 and 76 and 77 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some diseases known in the prior art, does not reasonably provide enablement for the full scope of the diseases treated in the claimed method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

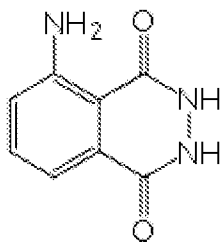
The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a

disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: A method for therapy of disease caused by intracellular acidosis, oxygen deficiency in cell, excessively-formed free radicals, increasing the aggregation of thrombocytes and/or erythrocytes, or harmful action or disorders of nitrergic mechanisms of cell, said method comprising administering to a subject a pharmaceutically-effective amount of the sodium salt of 5-amino-benzo[d]-3H-pyridazine-1,4-dione.

The state of the prior art: Minin et al. (US Patent 5,512,573, issued 30 Apr 1996, of record) discloses the use of 5-aminophthaloylhydrazide and its salts administered in effect amounts as anti-hypoxic and defensive agents (abstract). The compound 5-aminophthaloylhydrazide or Luminol (column 1, lines 20-25), has the chemical structure



corresponding to the elected species. Minin et al. discloses the use of the sodium salt of 5-aminophthaloylhydrazide (column 4, lines 30-35). Minin et al. discloses the administration for the therapeutic effect of antioxidant action to treat acyte

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hypoxia of myocardial infarct or heart attack (column 4, lines 50-55) and treatment of an excess of free oxygen radicals (column 4, ca. line 60). Minin et al. discloses that it is known that analogous drugs used for the same effect involve many complications and are not sufficiently effective (column 5, ca. line 55 and column 6, lines 5-10).

Henry et al. (US Patent 6,953,799, filed 30 Oct 2002, cited in PTO-892) discloses phthalazine compounds such as 5-amino-2,3-dihydro-1,4-phthalazinedione, also known as luminol, (column 1, lines 45-50) administered to treat hosts with diseases involving impaired or aberrant intracellular redox states, which affects the membrane proton gradient, resulting in intracellular acidosis, and causes oxygen deficiency in cells and excessive formation of the free radical superoxide (column 2, lines 40-55). In the background section Henry et al. discloses luminol is known in the prior art to be useful in treating specific conditions such as "an inhibitor of poly (ADP-ribose) polymerase, an enzyme that responds to DNA damage (see U.S. Pat. Nos. 5,874,444; 5,719,151; 5,633,282), and to application in treating skin aging, Alzheimer's, atherosclerosis, osteoarthritis, osteoporosis, age-related macular degeneration, muscular dystrophy, immune senescence, viral infections, and cancer as diseases involving the functions of poly (ADP-ribose) polymerase (see U.S. Pat. Nos. 5,874,444; 5,719,151; 5,633,282)." Henry et al. teaches this therapy for treating, for example, atherosclerosis, burns, and chronic viral infections of the liver (column 4, lines 35-50), a hepatoprotective therapy. Henry et al. discloses it is known that said compound has an effect to treat the nitroergic mechanisms of cells in the central nervous system (column 10, lines 10-45).

Long (The Essential Guide to Prescription Drugs, 1982, 3rd ed, p3-7, cited in PTO-892) teaches that it is well known in the art that there is an inescapable element of uncertainty that the desired effect of a drug will be exactly as intended or predicted (page 4, paragraph 2). Long teaches that one reason for this unpredictability is that a drug is selected because its principal action is for the intended treatment will necessarily have multiple action which may render it not useful for the intended treatment (page 4, paragraph 3). Long teaches that another reason for this unpredictability is that all patients experience multiple responses to a drug and a body's reaction to a drug may vary widely from person to person (page 4, paragraph 4).

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: The sheer number of possible diseases which are caused by the recited mechanisms and possible patient populations means that one skilled in the art cannot predict the usefulness for all possible methods for therapy of a disease encompassed within the instant invention. As recited above, Long teaches there is an inescapable element of uncertainty that the desired effect of a drug will be exactly as intended or predicted. Therefore the claimed invention is unpredictable.

The Breadth of the claims: The scope of the claims is infinite. Any possible diseases which are caused by the recited mechanisms and possible patient populations could potentially be treated in the instant invention.

The amount of direction or guidance presented: The specification speaks generally about the role of homeostatic parameters in the survival and functioning of

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organisms, such as acid-base balance at page 1. It is suggested that the compound of the instant invention affects the pH within a cell (page 23). However, guidance is not given for the treatment of the full scope of the diseases encompassed within the instant method.

The presence or absence of working examples: The only working examples provided are for *in vitro* fibroblasts (page 24), *in vitro* thrombocytes (page 32), *in vivo* antiaggregation of thrombocytes (page 35 and page 40), activity with regard to superoxide (page 50) and oxidative stress (page 52).

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable art such as treatment of a disease based on the mechanism of action based on using a drug selected because its principal action is for the intended treatment. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the invention with the full range of all possible diseases treat beyond those known in the art, (such as surveyed as the prior art as disclosed Henry et al.) one skilled in the art would undertake a novel and extensive research program into the therapeutic effectiveness of the compound for all possible diseases caused by the recited mechanisms. Because this research would have to be exhaustive, and because it would involve such a wide and unpredictable scope of possible diseases, patient populations and treatment regimes, it would constitute an undue and unpredictable experimental burden.

Genentech, 108 F.3d at 1366, states that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims, Applicants fail to provide information sufficient to practice the claimed invention for all possible diseases caused by the recited mechanisms for all patient populations.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 71-73 and 76 and 77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 71 recites “disease caused by intracellular acidosis, oxygen deficiency in cell, excessively-formed free radicals, increasing the aggregation of thrombocytes and/or erythrocytes, or harmful action or disorders of nitrergic mechanisms of cell”. Claims 72, 76 and 77 depend from claim 71 and incorporate all limitations therein. The recited term renders the claim indefinite because the recited term does not particularly point out what diseases are encompassed by the recited term. The etiology of a disease may vary widely from person to person due to the complexity of the human body, and a disease caused by intracellular acidosis or excessively-formed free radicals in one person may have a different cause in another person. Therefore, one of skill in the art would not be readily apprised of the metes and bounds of the claimed method.

Claim 73 recites “wherein the disease is included in the group consisting of ...” It is unclear if this means said disease is selected from one of the diseases in said group

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or if said disease is a disease in addition, or included, to the recited group. This indefiniteness may be clarified by using language such as “wherein the disease selected from the group consisting of ...”

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

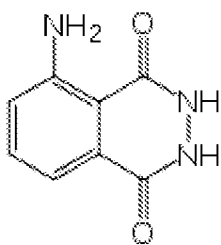
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 71-73 and 76 and 77 are rejected under 35 U.S.C. 102(b) as being anticipated by Minin et al. (US Patent 5,512,573, issued 30 Apr 1996, of record).

Minin et al. discloses the use of 5-aminophthaloylhydrazide and its salts administered in effective amounts as anti-hypoxic and defensive agents (abstract). The compound 5-aminophthaloylhydrazide or Luminol (column 1, lines 20-25), has the



chemical structure

corresponding to the elected species. Minin et al.

discloses the use of the sodium salt of 5-aminophthaloylhydrazide (column 4, lines 30-

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35). Minin et al. discloses the administration for the therapeutic effect of antioxidant action to treat acute hypoxia of myocardial infarct or heart attack (column 4, lines 50-55) and treatment of an excess of free oxygen radicals (column 4, line 60).

It is noted that the active step of the instant method requires only administration to a subject a pharmaceutically effective amount of said compound. No nexus is recited in the instant method as claimed between the disease and the subject.

Note that “intracellular acidosis, oxygen deficiency in cell, excessively-formed free radicals, increasing the aggregation of thrombocytes and/or erythrocytes, or harmful action or disorders of nitrenergic mechanisms of cell” or “hepatoprotective action” is merely considered to be new function or the unknown property or the mechanism of action of a treatment, 5-aminophthaloylhydrazide and its salts administered in effective amounts. It has been settled that the claiming of a new function or unknown property which is inherently present in the prior art method will not make the claim patentable as set forth in the 102(b) rejection above.

That applicant may have determined a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the encompassed within the instant method as claimed. Thus, the method steps in Minin et al. are the same as the method claimed herein. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.

Moreover, the mechanism of action of a treatment does not have a bearing on the patentability of the invention if the method steps, i.e., administering the same compound in the same amount to the same or similar patient population, are already known even though Applicant has proposed or claimed the mechanism (e.g., “intracellular acidosis, oxygen deficiency in cell, excessively-formed free radicals, increasing the aggregation of thrombocytes and/or erythrocytes, or harmful action or disorders of nitrergic mechanisms of cell” or “hepatoprotective action”). Applicant’s recitation of a new mechanism of action for the prior art method will not, by itself, distinguish the instant claims over the prior art teaching the same or substantially identical method steps. Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Minin et al. is silent as to “said compound having the ability to normalize hydrogen ion concentration in cells to within physiologically-acceptable concentrations”. However, this property of the compound is found to be an inherent property that is necessarily present from the chemical structure. “A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present”, see MPEP 2112.01.

Claims 71-73 and 76 and 77 are rejected under 35 U.S.C. 102(e) as being anticipated by Henry et al. (US Patent 6,953,799, filed 30 Oct 2002, cited in PTO-892).

Henry et al. discloses phthalazine compounds such as 5-amino-2,3-dihydro-1,4-phthalazinedione, also known as luminol, (column 1, lines 45-50) administered to treat hosts with diseases involving impaired or aberrant intracellular redox states, which affects the membrane proton gradient, resulting in intracellular acidosis, and causes oxygen deficiency in cells and excessive formation of the free radical superoxide (column 2, lines 40-55). Henry et al. discloses said phthalazine compounds incorporated into pharmaceutical forms (column 2, lines 65-70 and column 3, lines 1-5), and discloses the sodium form of a phthalazine compound (column 17, lines 50-55), leading one of skill in the art to instantly envision the well-known pharmaceutically acceptable sodium salt. Henry et al. teaches this therapy for treating, for example, atherosclerosis, burns, and chronic viral infections of the liver (column 4, lines 35-50), a hepatoprotective therapy. Henry et al. discloses it is known that said compound has an effect to treat the nitroergic mechanisms of cells in the central nervous system (column 10, lines 10-45).

Note that "intracellular acidosis, oxygen deficiency in cell, excessively-formed free radicals, increasing the aggregation of thrombocytes and/or erythrocytes, or harmful action or disorders of nitroergic mechanisms of cell" or "hepatoprotective action" is merely considered to be new function or the unknown property or the mechanism of action of a treatment, 5-aminophthaloylhydrazide and its salts administered in effective

amounts. It has been settled that the claiming of a new function or unknown property which is inherently present in the prior art method will not make the claim patentable as set forth in the 102(e) rejection above.

That applicant may have determined a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the encompassed within the instant method as claimed. Thus, the method steps in Minin et al. are the same as the method claimed herein. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.

Moreover, the mechanism of action of a treatment does not have a bearing on the patentability of the invention if the method steps, i.e., administering the same compound in the same amount to the same or similar patient population, are already known even though Applicant has proposed or claimed the mechanism (e.g., “intracellular acidosis, oxygen deficiency in cell, excessively-formed free radicals, increasing the aggregation of thrombocytes and/or erythrocytes, or harmful action or disorders of nitrergic mechanisms of cell” or “hepatoprotective action”). Applicant’s recitation of a new mechanism of action for the prior art method will not, by itself, distinguish the instant claims over the prior art teaching the same or substantially identical method steps. Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201

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USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Henry et al. is silent as to “said compound having the ability to normalize hydrogen ion concentration in cells to within physiologically-acceptable concentrations” in terms of hydrogen ion concentration, however this property is implicit in the membrane proton gradient. Further, this property of the compound is found to be an inherent property that is necessarily present from the chemical structure. “A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present”, see MPEP 2112.01.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 71-73 and 76 and 77 are provisionally rejected on the ground of nonstatutory double patenting over claims 28-33 of copending Application No. 10/567113. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Claim 28 of copending Application No. 10/567113 recites a method of treating diseases caused by disorders of the nitroergic system comprising administering a compound encompassing the compound of the instant method. Claim 29 of copending Application No. 10/567113 recites the elected species of compound. Claim 33 of copending Application No. 10/567113 recites diseases such as ischemia, also recited in instant claim 73. Therefore claims 28-33 of copending Application No. 10/567113 recite a subgenus of the instant method.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jonathan Lau
Patent Examiner
Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623

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